BAA-NIAID-DMID-NIH-AI-2014028
"TARGETED CLINICAL RESEARCH TO ADDRESS SELECT VIRAL INFECTIONS"

AMENDMENT ONE (1)

OFFICE OF ACQUISITIONS
National Institute of Allergy and Infectious Diseases (NIAID)
5601 Fishers Lane, Room 3D38, MSC 9821
Bethesda, MD 20892-9821

Solicitation Number:	BAA-NIAID-DMID-NIH-AI-2014028
Date of Solicitation Issuance:	December 15, 2014
Date of Amendment One (1) Issuance:	March 20, 2015
Proposal Due Date and Time:	Tuesday, May 12, 2015, 3:30 PM Eastern (UNCHANGED)
Number of Pages:	7
Point of Contact:	PRIMARY: Swee L. Teo, Contracts Specialist Email: teosl@niaid.nih.gov Phone: 240-669-5173 SECONDARY: George W. Kennedy, J.D., Contracting Officer Email: kennedyg@mail.nih.gov Phone: 240-669-5170

The purpose of Amendment One is to:

1. Provide a cut-off date for the submission of questions;
2. Respond to questions received regarding this solicitation.

Offerors MUST acknowledge receipt of the amendment by Amendment number (s) and date of the amendment. Failure to receive your acknowledgment of this amendment may result in the rejection of your proposal.

Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

I. Cut-off date to submit questions regarding this solicitation:

All questions regarding this solicitation must be submitted via email to the Point of Contact listed above by **April 10, 2015**.

II. The Government's responses to questions received regarding this solicitation are as follows:

A. Section I. Introduction

1. **Question:** The announcement states "three to five contracts may be issued for a total cost (direct and indirect costs combined) of up to $6.3 million in Fiscal Year 2016 for all awards during the first non-severable phase." Is the $6.3 million in Fiscal Year 2016 only the first year funding for all the awarded projects or is this the total budgets over the entire period of performance (up to 5 years)? Can the Government provide an anticipated total funding range for each award?

   Response: In accordance with Section I. Introduction of the BAA, the $6.3 million in Fiscal Year 2016 is the total anticipated amount for the first non-severable phase of **all award(s)**. The amount is not for the entire period of performance (up to five years). Because it is anticipated that the total costs for each award may vary depending upon the scope and capacity of the technical objectives of the award, there is not an anticipated total funding range for each award.

B. Section II. Background and Technical Objectives

2. **Question:** Will studies with vaccines be considered?

   Response: As stated in Section II.B Technical Objective of the BAA, vaccines studies will not be considered.

3. **Question:** Will studies for parasitic diseases be considered?

   Response: No, studies for parasitic will not be considered. According to Section II.B. Technical Objective, the focus of this announcement is on viral diseases only.

4. **Question:** The product is intended for use in human, but are not at the clinical trial phase yet. This product is being developed and will use lab animals for evaluation prior to clinical trials. Will non-clinical, such as animal studies be considered for this solicitation?

   Response: Non-clinical, such as animal studies, will NOT be considered in this announcement. Only clinical research in humans will be considered in this announcement in accordance with Section II.B. Technical Objectives; however, as stated on page 4 of the BAA, first in human studies phase 1 will NOT be considered.

5. **Question:** Should a study focus on one disease, or can it consist of several viral infections in a group format?

   Response: An offeror's proposed study does not need to focus on one virus as long as it meets the criteria of the scope of work, that is, for rare and/or emerging viral diseases in a targeted patient population in accordance with Section II.B. Technical Objectives of the BAA.

6. **Question:** Should a study addressing two different viral infections be submitted as one proposal or two separate proposals?

   Response: A single proposal should not contain two different studies; but a study may include multiple viral infections as long as it meets the criteria of the scope of work, that is, be for rare and/or emerging viral diseases in a targeted patient population in accordance with Section II.B. Technical Objectives of the BAA.

C. Section III. General Proposal Instructions and Information

7. **Question:** Is there a page limit for the scientific proposal? On page 21, the overview page limit is 2. The Technical Proposal in all is 75 pages. However, is there an allocated page limit for the scientific research plan section of the Technical Proposal?

   Response: In accordance with Section IIIA.5. Formatting Number of Copies, and Page Limitations, the Technical Proposal is not to exceed 75 pages, inclusive of all attachments except CVs. While the scientific research plan is included in the 75 page total, it does not have a specific page limitation unto itself.

D. Section V. Reporting Requirements

8. **Question:** Who will determine whether a proposal study will require an Investigational New Drug (IND)?

   Response: For interventional studies, the Government will decide which proposal study will require an IND.

9. **Question:** If the award results in a clinical trial that is conducted under an IND, who will be the sponsor of the IND?

   Response: As stated in Section V.C.1. Clinical Protocol Implementation Requirements on page 17, The NIAID Division of Microbiology and Infectious Diseases (DMID) will be the sponsor and holder of the IND.

10. **Question:** Should offerors propose and budget for costs for clinical site monitoring for the study?

Response: According to Section V.C.2. Clinical Research Support Services on page 18, an offeror should develop plans necessary to ensure the adequate implementation and data integrity for the proposed research in the Technical Proposal. For clinical trials of interventional products conducted under IND, NIAID maintains the responsibility for clinical trial monitoring and data quality assurance. In the Business Proposal, an offeror should budget for clinical site monitoring costs accordingly.

11. **Question:** Page 18 of the BAA, Section 2. Clinical Research Support Services states that "For high risk clinical trials under DMID-held INDs, DMID will provide the data management, clinical site monitoring, and regulatory document review." Should a budget be proposed for (i) review of IRB documents for individual clinical sites, (ii) costs for DSMB activities, and (iii) generation of data reports for DSMB meetings?

    Response: An offeror should propose cost for the review of IRB documents for individual clinical sites, but not for DSMB activities and generation of data reports for DSMB meetings.

E. Section VI. Technical Proposal Instructions

12. **Question:** Under what circumstances will data management services be provided by NIAID?

    Response: As stated in Section VI.4.B.2. Data Management Support and Plan on page 23, all interventional studies that will be conducted under IND shall use NIAID DMID's contracted data management system.

13. **Question:** The announcement requires offerors to use NIAID's contracted data management services; will awardees have access to the dataset?

    Response: At the end of a trial, a complete dataset will be transferred to the Contractor/Principal Investigator, if requested.

14. **Question:** If proposing a study using the required NIAID contracted DMID Statistical Data and Coordinating Center, should statistical plans be included in the proposal?

    Response: Yes, as stated in Section VI.4.B.1. Statistical Plan Support on page 23, all studies shall provide sufficient information on the statistical plan and analysis that are appropriate to achieve the goals of the proposed clinical research project and will allow for an independent scientific review of the proposal.

15. **Question:** On p. 23 of the RFP, it states that for interventional studies that will be conducted under IND, the DMID Statistical and Data Coordinating Center (SDCC) will be responsible for the operation of a central data management system for IND studies. Should proposal include data management activities?

Response: Since awardees will be required to use the DMID Statistical and Data Coordinating Center for interventional studies conducted under IND, data management activities should not be included in your proposals. However, offerors should use their best judgment to include appropriate statistical support for your study.

F. Section VII. Business Proposal Instructions

16. **Question:** Under VII. Business proposal instructions, the instructions include a link to an excel spreadsheet. The instructions also state that "business proposals must provide a detailed task-linked budget that consists of a breakdown of total costs. Is the excel spreadsheet enough to satisfy the "task-linked budget" or is it necessary to also provide an additional table that outlines the task-linked budget separate from the excel spreadsheet? Is there a template for the task-linked budget?

    Response: As stated in Section VII. Business Proposal Instructions of the BAA, an Offeror must provide a detailed task-linked budget that consists of a breakdown of total costs (direct costs, indirect costs, and fees) linked to the Base period, and each Option, task and subtask (as applicable). This budget will be linked to tasks down to a level that the offeror considers reasonable and manageable, but will also facilitate cost accountability and proper contractor and Government oversight and management of cost/performance issues. In addition to this task-linked budget, a summary budget reflecting the total costs over the entire period of performance of the proposed contract shall be provided in the "Breakdown of Proposed Estimated Costs (plus fee) and Labor Hours" format. There is no template for the task-linked budget. An offeror can use any format to present this budget.

17. **Question:** For the purposes of this BAA, who are considered "Key Personnel"? Which Personnel should be included to attend start up and annual meetings in the budget?

    Response: Key personnel is limited to those experienced professional and/or technical personnel considered uniquely essential to performing the work required. Their resumes are submitted together with the proposal for evaluation. Please be aware that when an individual(s) from the key personnel list is named in the contract during negotiations, that individual cannot be replaced without the written consent of the Contracting Officer. For the purpose of estimating costs, travel for site visit and programmatic presentations and reviews as stated in paragraphs A. and D. Section IV. Uniform Assumptions of the BAA shall include relevant key personnel of the Prime Contractor only; subcontractor(s) excluded.

G. Other

18. **Question:** If the award results in a clinical trial that will be conducted in a foreign country, who will be the regulatory sponsor in that country?

    Response: The offeror should propose some options for sponsorship in the country where the research will be done. If selected for award, NIAID will negotiate the specifics of that sponsorship with the offeror.

19. **Question:** Is a non-US institution eligible to apply for this solicitation?

Response: Yes, a non-US institution is eligible to submit a proposal in response to this BAA. If successful, clearance by the State Department will be obtained prior to awarding a foreign contract, a foreign subcontract, or a domestic contract or subcontract with a foreign component.

20. **Question:** Are there templates for the technical and business documents.

    Response: There are no templates for the technical and business proposals. An Offeror should carefully review the content of the solicitation for information regarding the technical objectives of this broad agency announcement, instructions regarding proposal submission, and a description of the evaluation and award process; and exercise its professional judgment in compiling its proposal.

21. **Question:** For proposals that evaluate the safety and efficacy of an interventional product that will be provided by a pharmaceutical company, what are the requirements for participation by the pharmaceutical company?

    Response: Establishment of a clinical trial agreement between NIAID and a pharmaceutical company is required prior to implementing a study. For studies that use an interventional product provided by a pharmaceutical company, a clinical trial agreement must be established between NIAID and the pharmaceutical company to addresses the level of participation of the company in the development and implementation of the protocol; the sharing with company of the dataset and the final dataset at the end of the trial (if requested); safety oversight responsibilities; protection of confidential information; and protection of intellectual property rights. Because DMID will hold any IND necessary for an interventional study, the pharmaceutical company is expected to provide the most current Investigator's Brochure (or package insert) and a letter of authorization for cross referencing the company's IND or Drug Master File to NIAID.

22. **Question:** Is it permissible for a clinical investigator or a company sponsoring research at a site to respond to this announcement?

    Response: Both clinical investigators and companies sponsoring research at a site can respond to this BAA.

23. **Question:** Please confirm who should submit the proposal in eCPS portal – the Principal Investigator or the Institutional Official? Or, can either one submit via eCPS?

    Response: Either the Principal Investigator or the Institutional Official can submit the proposal in eCPS.

24. **Question:** Is it possible to submit a research proposal with Co-Principal Investigators?

    Response: Yes, an Offeror can submit a research proposal with Co-Principal Investigators.

25. **Question:** Is it permissible to include Government resources in a proposal?

    Response: Government resources that are included in one offeror's proposal, must be made available to all potential offerors. Therefore, Government resources that are not available to the public should not be included in your proposal.